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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,588	09/15/2003	Sven Schreder	MERCK-2168D1	8058
23599 7590 02/12/2009 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201				
EXAMINER				
SPIVACK, PHYLLIS G				
ART UNIT		PAPER NUMBER		
1614				
MAIL DATE		DELIVERY MODE		
02/12/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/661,588

Applicant(s)

SCHREDER ET AL.

Examiner

Phyllis G. Spivack

Art Unit

1614

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-5 and 9-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5 and 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Applicants' Amendment filed November 5, 2008 is acknowledged. Claim 6 is canceled. Claims 1, 3-5 and 9-16 remain under consideration.

Rejections and objections that are not reiterated from previous Office Actions are hereby withdrawn. The following rejection constituted the only rejection presently applied to the instant claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-5 and 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reynolds et al., U.S. Patent 3, 808,332, in view of Lindenbaum E., WO 93/04691, and further in view of Jacobs et al., US 2005/0003491.

Reynolds teaches a combination of L-thyroxine and L-triiodothyronine that are physically admixed. Therefore, no organic solvent are present. See column 7, lines 65-67. See Composition I, column 7, where cornstarch is employed as a filler, and Composition J, where lactose and microcrystalline cellulose are employed as fillers. As required by instant claim 3, Reynolds teaches a concentration range of L-thyroxine of 100-300 mcg. Fillers such as lactose, maize starch and microcrystalline cellulose are conventional excipients. Reynolds fails to include gelatin in the combination. However, Lindenbaum teaches pharmaceutical preparations comprising levothyroxine or triiodothyronine and gelatin that are manufactured in solid forms, such as creams or powders, without organic solvents. See claims 13 and 19, as well as page 17, lines 16-

18. A micronized form of levothyroxine with a particle size between 5 and 25 μm is conventional.

Jacobs teaches the inclusion of gelatin in solid pharmaceutical formulations comprising proteins, such as tablets. See page 174, paragraph 4072.

Therefore, in view of the combined teachings of Reynolds, Lindenbaum and Jacobs, one skilled in the art of formulation chemistry would have been motivated to prepare pharmaceutical formulations comprising L-thyroxine and, optionally, triiodothyronine, utilizing gelatin, in a solid form without organic solvents. Because of its well-established cohesive qualities, gelatin is conventionally employed in tablet formulations. The present claims are entirely drawn to compositions comprising levothyroxine, and optionally, liothyronine, and gelatin. Accordingly, intended use is not a consideration and does not impart patentability to a composition that is obvious from prior art teachings.

In the Communication filed February 13, 2008, Applicants argued Lindenbaum's teachings are directed merely to wound healing in that administration is topical involving creams or gels. However, the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. **Powders** are solids, and in the production of a tablet, the composition is in the form of a powder prior to compression.

Further, upon reconsideration, the showing presented in the Declaration filed February 13, 2008 under 37 CFR 1.132, is not commensurate in scope with the present claims. In Formulation B it is unclear whether or not hydroxypropyl methylcellulose imparts a destabilizing effect.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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